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Takeshi Takaha

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EXAMINER

SCHMIDTMANN, BAHAR

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,595	Applicant(s) TAKAHA ET AL.	
	Examiner BAHAR SCHMIDTMANN	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/06/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a 35 U.S.C. § 371 National Stage Filing of International Application No. PCT/JP04/10149, filed 09 July 2004, which claims foreign priority under 35 U.S.C. § 119(a-d) to JP 2003-272593 filed 09 July 2003; currently a certified English language translation of this foreign priority document has not been made of record.

The preliminary amendments filed 06 January 2006 is acknowledged. Claims 1-35 are pending in the current application. Claims 1-12 are withdrawn as being drawn to a nonelected invention, see below. Claims 13-35 are examined on the merits herein.

Election/Restrictions

Applicant's election of Group 2 in the reply filed on 12 June 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without** traverse (MPEP § 818.03(a)).

Claims 1-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12 June 2009.

Claims 13-35 are examined on the merits herein.

Information Disclosure Statement

The information disclosure statement filed 06 January 2006 is acknowledged, and considered by the examiner.

Claim Objections

Claims 13-22 and 24-35 are objected to because of the following informalities:
The recitation of “high molecular weight α -1,4-glucan **and/or** its modification and low molecular weight α -1,4-glucan **and/or** its modification” could be corrected to say “high molecular weight α -1,4-glucan and its modification and low molecular weight α -1,4-glucan and its modification”; high molecular weight α -1,4-glucan and its modification and low molecular weight α -1,4-glucan or its modification”; high molecular weight α -1,4-glucan or its modification and low molecular weight α -1,4-glucan or its modification”; or high molecular weight α -1,4-glucan or its modification and low molecular weight α -1,4-glucan and its modification”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-22 and 24-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of “high molecular weight α -1,4-glucan and/or its modification and low molecular weight α -1,4-glucan and/or its modification” in claims 13-22 and 24-35 render the claims herein indefinite. The specification generally discloses the modification is achieved by an enzyme such as sucrose phosphorylase (p.5, lines 15-

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20) or by chemical modification (p.18, lines 6-17). The specification discloses non-limiting examples, “may preferably be”. The scope of “modification” of the invention as claimed is unclear. One having ordinary skill in the art would not be able to envisage all the possible structures of a polysaccharide comprising α -1,4-glucans where said polysaccharide may be modified at any position and with any ester, ether or crosslinking agent.

The recitation of a “molecular weight distribution of not greater than 1.25” in claims 16-18 and 24-27 renders the claim herein indefinite. The claims do not recite a lower limit. Therefore one of ordinary skill in the art would not be able to ascertain the metes and bounds of instantly claimed invention.

Claim 23 provides for the use of low molecular weight α -1,4-glucan, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. In view of the language of the other examined claims, this has been interpreted as a method of adding a low molecular weight α -1,4-glucan to gel a solution containing α -1,4-glucan.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-14 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Hausmanns (WO 02/102355, cited in PTO-892) as evidenced by IUPAC Gold Book (cited in PTO-892).

Hausmanns discloses formation of a molded article from poly(1,4- α -D-glucan) and starch (abstract). Hausmanns discloses the poly(1,4- α -D-glucan) has a degree of polymerization between 40 and 300 (p.3 part c, ii). Hausmanns discloses producing a molded article wherein the poly (1,4- α -D-glucan) is combined with Amyloplast PE 004 potato starch (p.18, example 1), wherein said potato starch (20% unbranched amylase) has a degree of polymerization of 4000 (p. 20, comparative example 2, table 1), meeting the instant definition of a high molecular weight glucan. Hausmanns discloses the temperature of the aqueous solution of poly (1,4- α -D-glucan) and starch solution was maintained at elevated temperatures, i.e. the temperature was maintained between 50 and 95 °C (p.15, first bullet). Hausmanns discloses the temperature of the first hood was established to cool said aqueous solution of poly (1,4- α -D-glucan) and starch (p.15, second-sixth bullet).

The IUPAC Gold Book discloses the degree of polymerization is a number based on the monomeric units in a macromolecule, oligomer molecule, block or chain.

While Hausmanns does not expressly disclose the molecular weight of poly (1,4- α -D-glucan) and starch, the disclosed degrees of polymerization, respectively distinguish the two polysaccharides as low molecular weight α -1,4-glucan and high molecular weight α -1,4-glucan. Therefore, the poly (1,4- α -D-glucan) and starch are

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inherently low molecular weight α -1,4-glucan and high molecular weight α -1,4-glucan, respectively.

Thus, the disclosure by Hausmanns anticipates claims 13, 14 and 23.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-22 and 24-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hausmanns (WO 02/102355, cited in PTO-892) in view of Bengs et al. (WO 01/85836 cited in Information Disclosure Statement, see US Patent No.

6,908,885 cited in PTO-892 referenced as the English language equivalent of WO 01/85836) as evidenced by IUPAC Gold Book (cited in PTO-892).

Hausmanns discloses formation of a molded article (e.g. a hard capsule) from poly(1,4- α -D-glucan) and starch (abstract). Hausmanns discloses the poly(1,4- α -D-glucan) has a degree of polymerization between 40 and 300 (p.3 part c, ii). Hausmanns discloses producing a molded article wherein the poly (1,4- α -D-glucan) is combined with Amyloplast PE 004 potato starch (p.18, example 1), wherein said potato starch (20% unbranched amylase) has a degree of polymerization of 4000 (p. 20, comparative example 2 in table 1), meeting the instant definition of a high molecular weight glucan. Hausmanns discloses the temperature of the aqueous solution of poly (1,4- α -D-glucan) and starch solution was maintained at elevated temperatures, i.e. the temperature was maintained between 50 and 95 °C (p.15, first bullet). Hausmanns discloses the temperature of the first hood was established to cool said aqueous solution of poly(1,4- α -D-glucan) and starch (p.15, second-sixth bullet). Hausmanns discloses the molded article can be used as a pharmaceutical, cosmetic, food, food additive, food supplement and/or food ingredient (p.16).

Hausmanns discloses the molded article is made from a composition comprising 50-95% starch (i.e. the high molecular weight α -1,4-glucan), more preferably 60-90%, most preferably 70-90% and 5-50% poly(1,4- α -D-glucan) (i.e. the low molecular weight α -1,4-glucan), more preferably 10-40%, most preferably 10-30% (p.4). Hausmanns also discloses the molded article can be made from at the very least 1% poly(1,4- α -D-glucan) and at the very most 99% starch (claim 1). Hausmanns discloses the poly(1,4-

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α -D-glucan) can be produced enzymatically (p.7) and that the starch can be used with or without chemical modification by esterification and etherification (p.11). Amylopectin is a branched polymer; amylose is unbranched and corresponds to the HMW glucan. The disclosed starch is only 20% amylose.

At the broadest taught range, Hausmanns discloses a ratio of high molecular weight to low molecular weight α -1,4-glucan ranging from 19.8:1 to 1:5 (i.e. 95% HMW glucan to 5% LMW glucan and 16% HMW glucan to 83% LMW glucan). One having ordinary skill in the art could easily envisage a high molecular weight α -1,4-glucan to low molecular weight α -1,4-glucan ratio as 50:50 and 75:25 since these ratios are encompassed by the ranges disclosed by Hausmanns. Furthermore, in the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art”, such as the degree of polymerization of the poly(1,4- α -D-glucan), a prima facie case of obviousness exists (see MPEP 2144.05, part I).

Hausmanns does not expressly disclose the molecular weight of the α -1,4-glucans (all instant claims). However, molecular weight is an inherent property implicitly disclosed in the degree of polymerization. Hausmanns does not expressly disclose the molecular weight distribution of the α -1,4-glucans (instant claims 16 and 17).

The IUPAC Gold Book discloses the degree of polymerization is a number based on the monomeric units in a macromolecule, oligomer molecule, block or chain.

Bengs et al. discloses a gel comprising poly(1,4- α -D-glucan) and starch (abstract). Bengs et al. discloses the polyglucan and starch were prepared either enzymatically or chemically, e.g. esterification and/or etherification (column 4, lines 10-

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19). Bengs et al. also discloses the degree of polymerization of the polyglucan ranges from 40 to 300 (claim 9). Bengs et al. discloses the most preferred polydispersity of the polyglucan as ranging from 1.01 to 2. Bengs et al. also teaches 1.01 to 5 and 1.01 to 2.5. Bengs et al. discloses the gel may be edible, biodegradable, and may additionally comprise active ingredients such as pharmaceutical, cosmetic, agrochemical, odor and/or flavor modifying agents (claim 8).

It would have been obvious at the time the invention was made to prepare a molded article by adding a low molecular weight α -1,4-glucan to a high molecular weight α -1,4-glucan.

One having ordinary skill in the art would have been motivated made to prepare a molded article by adding a low molecular weight α -1,4-glucan to a high molecular weight α -1,4-glucan because this has been disclosed by Hausmanns. While Hausmanns does not expressly disclose the molecular weight distribution of the α -1,4-glucans, the taught glucans were prepared enzymatically and/or chemically modified by esterification and/or etherification in a similar process as Bengs et al. and instant application. One having ordinary skill in the art would also be motivated to narrow the polydispersity of the glucans as suggested by Bengs et al., wherein the polydispersity is taught as a broad range of 1.01 to 5, but is preferably limited to the range to 1.01 to 2. The degree of polymerization of the glucans lie within the range and/or overlap with instant application, providing additional evidence that the poly(1,4- α -D-glucan) having a lower degree of polymerization is a low molecular weight polymer, while starch having a higher degree of polymerization is a high molecular weight polymer.

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Furthermore, molecular weight distribution is a result effective parameter. Because the α -1,4-glucans disclosed by Hausmanns were prepared in the same manner as Bengs et al. and instantly claimed invention, i.e. enzymatically or chemical modification, one having ordinary skill in the art would know that the molecular weight distribution of the polysaccharides taught by Hausmanns are similar to Bengs et al. which overlaps with the ranges of instantly claimed invention.

Therefore, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. BAHAR SCHMIDTMANN whose telephone number is 571-270-1326. The examiner can normally be reached on Mon-Thurs 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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